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| 10/527,216 | 04/21/2005 | Michio Ishibashi | 2005_0275A | 2843 |

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

| EXAMINER | |
|---|---|
| JEAN-LOUIS, SAMIRA JM | |

| ART UNIT | PAPER NUMBER |
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| 4173 | |

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| 12/11/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/527,216 | ISHIBASHI, MICHIO | |
| | Examiner | Art Unit | |
| | SAMIRA JEAN-LOUIS | 4173 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *16,17 and 21-28* is/are pending in the application.

4a) Of the above claim(s) *17 and 21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Sheet (1)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Claims 16-17 and 21-28 are currently pending in the application.

Applicant's election of Group I (i.e. a method for screening a compound which is able to prevent, mitigate or treat glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions, which comprises measuring a promoting action of a compound) in the reply filed on 11/13/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 17, and 21-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority. It is noted, however, that applicant has not provided English translations of the Japanese applications 2002-265884 and 2003-159975 as required by 35 U.S.C. 119(b). Thus, the priority date of the instant invention is September 10, 2003 (the date of the PCT application). Without the English translation, one cannot ascertain if the instant

invention is present in the Japanese applications. Therefore, art prior to the PCT date, but not before the date of the Japanese applications may be cited against the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening a compound which is able to treat renal glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions, does not reasonably provide enablement for a method of screening a compound which is able to prevent the aforementioned lesions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For example, kidney disease is characterized by lesions, however, applicant does not reasonably provide enablement for a method to prevent the occurrence of lesions nor does the application enable any person skilled in the art to use the invention to prevent lesion formation and/or the aforementioned conditions. Currently, low protein diet, blood pressure control and multidrug approach are used in humans for disease regression.

The instant claims are drawn to a screening method comprising a compound which is able to prevent, mitigate or treat renal glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention as a screening method.

Attention is directed to *In reWands,* 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Specifically, in regard to the nature of the invention, applicant claims a screening method comprising a compound which is able to treat renal glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions which comprises measuring a promoting action utilizing human peripheral blood mononuclear cells with a lipopolysaccharide.

As for the breadth of the claims, the predictability of the art, and the amount of guidance of direction or working examples, claim 16 fails to embrace and read on a screening method using a compound which is able to prevent renal glomerular lesions,

lesions of pancreatic islets of Langerhans or epidermal lesions as set forth in the instant specification. Particularly, applicant claims prevention treatment (as disclosed in table 2-1, pg. 72) yet only a percentage was demonstrated to be reduced. Moreover, prevention of these conditions in patients or animal models already afflicted is unlikely. Additionally, given that the instant specification provides no limiting definition of the term "prevention", the examiner will adopt the broadest reasonable interpretation for same. Webster Ninth Collegiate Dictionary defines "prevent" as "to keep from happening or existing", i.e., to stop the occurrence in the first place.

The claims are thus very broad insofar as they recite the "prophylactic treatment, i.e., prevention of the aforementioned conditions. While such "prevention" might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live.

In addition, the predictability of preventing renal glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions is relatively low given that the progression rates of these conditions are high. Therefore, to one skilled in the art, prevention of these aforementioned conditions is highly unpredictable. As for the guidance of the specification as to the screening method for prevention of the aforementioned conditions, the above is severely limiting given that the specification is limited to treatments and not necessarily to prevention of such conditions.

In conclusion, the applicant is enabled for a method for screening a compound which is able to treat glomerular lesions, lesions of pancreatic islets of Langerhans or epidermal lesions, but not for a method for screening a compound which is able to prevent the aforementioned conditions.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Ishibashi et al. (EP 12777747 A1, already cited by applicant and filed on an IDS 1449 form).**

WO 01/72730 A1 is the PCT counterpart to EP 1277747 A1. WO 01/72730 A1 is prior art under U.S.C. 102 (b) as a result of its April 10, 2001 publication date. EP 1277747 A1 is prior art under U.S.C. 102 (a). Because WO 01/72730 A1 and EP 1277747 A1 appear to have identical disclosures, the European patent application is being used as a translation of WO 01/72730 A1 PCT. While any reference hereinafter to column and line numbers will be based upon the European patent application disclosure, such reference

should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Additionally, for proper claim examination, Examiner is giving a broad and reasonable interpretation of claim 16 in light of the specification as a method for screening a compound that requires the step of measuring a promoting action caused by the contact of human peripheral blood mononuclear cells with lipopolysaccharide. As for the recitation " to be tested on the induction of regeneration-promoting CD11b+CD2+ macrophages and regulatory CD2-CD4+ T lymphocytes, Examiner is construing "to be tested" as a possible step to be taken in the future and therefore is not required as a claim limitation.

Consequently, Ishibashi et al. discloses an invention that relates to a screening method for compounds that selectively suppress effector macrophages involved in progressive lesions without inhibiting the function and regeneration process of the organ (see pg. 2, paragraph 002 and pg. 46, paragraph 0306). Ishibashi et al. further discloses that suppression of macrophages occur via suppressing expression and function of various chemokine receptors such as CCR2, CCR3, CCR8, β2 integrin receptors such as CD11b/CD18 (see pg. 4, lines 37-41). In addition, the invention for the screening method is carried out by contacting peripheral blood mononuclear cells with lipopolysaccharide (see pg. 4, lines 48-52). Ishibashi et al. further disclose that the method of screening a compound is characterized by the showing of less production of

spontaneous plaque forming cell (SPFC) (see pg. 5, lines 11-13 and see test example 2). Importantly, the promoting action of suppression of compound 4-2 is exemplified in table 2 where compound 4-2 was shown to reduce glomerular lesion cases by 50% (pg. 42, table 2, line 14).

Accordingly, the teachings of Ishibashi et al. anticipate claim 16.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

11/07/2007

/Ardin H Marschel/

Supervisory Patent Examiner, Art Unit 1614